



UNITED STATES DEPARTMENT OF COMMERCE
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HL

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/313,628

05/18/99

HODGEN

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F/1890-201(D)

HM12/0708
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EXAMINER

MOEZIE, M

ART UNIT

PAPER NUMBER

1617

3

DATE MAILED:

07/08/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/313,628

Applicant(s)

Hodger

Examiner

Moeziz

Group Art Unit

1617

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-20 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-20 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of References Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

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This application is a divisional of serial no. 09/059,476.

Claims 4 and 10-16 are objected to for a minor informality. The term "activity" should be inserted following the term "progestogenic" for proper grammar.

Claims 2-3 and 6-7 are considered allowable over the prior art since the employment of the recited SERM compounds in combined contraceptive methods is not taught or fairly suggested thereby.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 1 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Garfield et al.

See, e.g., column 2 and column 6 therein for combined oral contraceptives which include estrogens and progestins. Estrogens are considered clearly within the scope of the claims since they are selective for, and modulate, the estrogen receptor.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-5, 8-13 and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garfield et al.

The prior art teaches that estrogens, progestins, antiprogestins, androgens and antigonadotropins within the claims are known to be useful in contraceptive regimens. See, e.g., columns 2 and 5-6. The combination of any of these agents into one contraceptive kit or regimen is prima facie obvious since each was known individually to be useful in a contraceptive regimen. At least additive contraceptive effects for the combination would be reasonably expected- See In re Kerkhoren 205 USPQ 1069.

The optimization of amounts of agents to be employed is considered within the skill of the artisan.

Claims 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka et al., Poulin et al. and Goodman Gilman et al.

See the parent application for cited references.

Tanaka et al teaches that clomiphene is an antiestrogen compound known to be useful in the treatment of a hormonally dependent cancer. See column 5, line 66 bridging column 6, line 7 therein. It further teaches that progestationally active compounds are known to be useful in antitumor compositions. See, e.g., the abstract and column 5. Poulin et al. suggest that the preferred benzothiophene antiestrogen compound herein, raloxifene, is useful to treat a

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hormonally dependent cancer. See, e.g., page 4935, column one, paragraph one therein. Finally, Goodman Gilman et al teach that progestationally active compounds are known to be useful in the treatment of hormonally dependent cancers. See page 1301, column 2 therein.

The instant claims differ from the prior art primarily in that they are drawn to kits for :
~~use in contraception; dependent~~ which employ an antiestrogen compound in combination with a progestationally active compound. The employment of two or more agents, each of which is known individually for the same purpose, together in a combination useful for the very same purpose in prima facie obvious. At least additive effects for the combination would be expected. See In re Kerkhoven 205 USPQ 1069. Therefore, the employment of antiestrogens herein in combination with progestationally active compounds in kits for the treatment of a hormonally dependent cancer is prima facie obvious.

The optimization of amounts of agents to be administered is considered within the skill of the artisan absent evidence to the contrary.

Note that the "intended use" for a kit will not render patentability to a claim drawn to a kit. See, e.g., In re Hack 114 USPQ 161.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Moezie whose telephone number is (703) 308-4612. The examiner can normally be reached on Monday to Friday from 9 a.m. to 5:30 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald E. Adams, Ph.D., can be reached on (703) 308-1235. The appropriate fax number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

MOEZIE;mvw

06/24/99

M. Moey
PRIMARY EXAMINER
GROUP 1600